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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,753	10/29/2001	Yasuhiro Sakai	3029-74	7298

7590 03/06/2007
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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT	PAPER NUMBER
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1651

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/005,753

Applicant(s)

SAKAI ET AL.

Examiner

Susan Hanley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22-27,30,31 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30 and 31 is/are allowed.
- 6) ☒ Claim(s) 20, 22-24, 26, 27 and 33-35 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The amendment and remarks filed 12/1/06 are acknowledged.

Claims 20, 22-27, 30, 31 and 33-35 are pending and are examined on the merits.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Election/Restrictions

Applicant's election of the species wherein the nitrite reducer is sulfamic acid, in Paper No. 5, filed June 9, 2003, is again acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). As noted in the previous office action, because a composition comprising a polymethine dye, sulfamic acid as a nitrite reducer (the elected species) and a buffer for maintaining an acidic pH is considered free of the prior art, examination has been extended to other species within the Markush group of claim 20. Further examination of additional elected species has been extended to urea, thiophenol, mercaptoethanol, sulfurous acid and cysteine. A composition comprising a polymethine dye, a nitrite reducer comprising urea, thiophenol, mercaptoethanol or sulfurous acid, and a buffer for maintaining an acidic pH is also considered free of the prior art. However, the extension of the elected specie to cysteine is not free of the prior art and has resulted in the following rejection:

Claim Rejections - 35 USC § 103

Claims 20-24, 26, 27 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizukami et al (EP 0 882 983 A2, previously cited) in view of Sosnowski et al. (WO 98/10273).

Mizukami discloses processes whereby a reagent comprising a polymethine dye and a quaternary ammonium surfactant, at a pH ranging from 4.5 to 11, is used to differentially stain

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leukocytes. See pages 3 and 4. Mizukami differs from the claims failing to disclose the inclusion in the reagent of a substance capable of reducing nitrite ions.

However, Mizukami clearly discloses the desirability of using a buffer in the composition. See, e.g., page 3, lines 42-44. One of ordinary skill in the art clearly would have recognized that cysteine was suitable for use as a buffer within the pH range (4.5 to 11) described by Mizukami as being useful for the staining reagent disclosed therein. For example, Sosnowski discloses that cysteine has a better buffering capacity at pH 5 than a 20 mM sodium phosphate. In the pH range of 4 to 6, the buffering capacity of cysteine is significantly better than 20 mM sodium phosphate (page 7-8, bridging paragraph). Recognizing the suitability of cysteine as a buffer in Mizukami's staining reagent, the artisan of ordinary skill would have been motivated to have included it in Mizukami's staining reagent. Thus, the artisan of ordinary skill would have been motivated to have included a compound which meets the claim limitations of being both a buffer for maintaining an acidic pH, and being a nitrite ion reducer. A holding of obviousness over the cited claims is therefore required.

Response to Arguments

All of applicant's argument has been fully considered but is not persuasive of error. Regarding the remaining § 103(a) rejection, applicant argues that the amended claims no longer recite the aminomethane specie. As such, applicant asserts that neither the primary nor secondary reference (Bates) disclose or suggest any substance capable of reducing nitrite ions as recited by the presently pending claims.

In response to applicant's argument that Mizukami and Bates are no longer relevant together because aminomethane is no longer recited in the presently pending claims, the new reference, Sosnowski, has been applied to the next specie, cysteine. In this case, Mizukami discloses that an acidic buffer is useful in the leukocyte staining polymethine dye-containing compositions disclosed therein. Sosnowski establishes that cysteine is a suitable buffers for use within the pH range set forth by

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Mizukami. Thus, because Sosnowski establishes that the cysteine buffer species was known in the art to be useful as buffers at the buffered pH range described by Mizukami, Sosnowski is clearly pertinent to the problem faced by Mizukami.

Claims 30 and 31 are allowed. Claim 25 is objected to as depending from a rejected claim.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

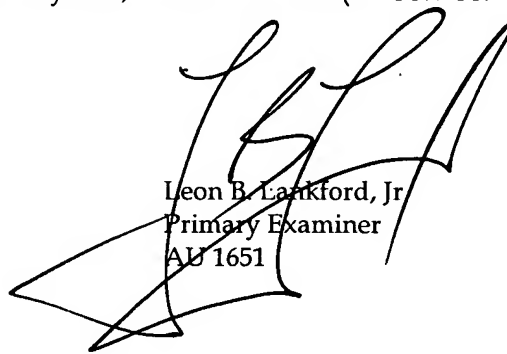
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hanley
Patent Examiner
AU 1651



Leon B. Lankford, Jr.
Primary Examiner
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